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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/540,718 | 12/21/2006 | Duncan J. Stewart | 3998-051954 | 2483 |

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| EXAMINER | |
|---|---|
| LOCKARD, JON MCCLELLAND | |
| ART UNIT | PAPER NUMBER |
| 1647 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/540,718 | STEWART ET AL. | |
| | Examiner | Art Unit | |
| | JON M. LOCKARD | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *33-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *33-64* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 33, 36-37, 40-44, 46-47, 50, and 53, in so far as they are drawn to a method for treating a pulmonary disorder comprising administering an apoptosis inhibitor or survival factor.

Group II, claim(s) 33-34, 36-37, 40-44, 46-48, 50, and 53, in so far as they are drawn to a method for treating a pulmonary disorder comprising administering an apoptosis inhibitor or survival factor, wherein said factor is administered by systemic gene therapy.

Group III, claim(s) 33, 35-47 and 49-53, in so far as they are drawn to a method for treating a pulmonary disorder comprising administering an apoptosis inhibitor or survival factor, wherein said factor is administered by cell-based gene therapy.

Group IV, claim(s) 54, drawn to an apoptosis inhibitor of undisclosed constitution.

Group V, claim(s) 55-57, drawn to a method for early diagnosis of a pulmonary disorder in a mammal.

Group VI, claim(s) 58, 61, and 64, in so far as they are drawn to a kit for the administration of an apoptosis inhibitor or survival factor.

Group VII, claim(s) 58-59, 61, and 64, in so far as they are drawn to a kit for the administration of an apoptosis inhibitor or survival factor, wherein administration is by systemic gene therapy.

Group VIII, claim(s) 58, and 60-64, in so far as they are drawn to a kit for the administration of an apoptosis inhibitor or survival factor, wherein administration is by cell-based therapy.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is directed to a method for treating a

pulmonary disorder comprising administering an apoptosis inhibitor or survival factor. However, since Tarasevicience-Stewart et al. (Faseb J. 15:427-438, 2001; cited by Applicant) teach a method for treating pulmonary hypertension comprising administering Z-Asp (See pg 433-434), no special technical feature exists for group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Because the technical feature of Group I is not a special technical feature, and because the technical features of the Groups II-VIII inventions is not present in the Group I claims, unity of invention is lacking.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of apoptosis inhibitors and survival factors are as follows:

(1) Z-Asp
(2) Z-VAD
(3) VEGF
(4) Bcl-2
(5) Bcl-xL
(6) acetyl- DEVD-aldehyde inhibitor
(7) acetyl-YVAD-aldehyde
(8) acetyl-YVAD-chloromethylketone
(9) Boc-D- (benzyl) chloromethylketone
(10) crmA
(11) Zn2+
(12) aurintricarboxylic acid
(13) cytochalasin B
(14) NO
(15) eNOS
(16) nNOS
(17) iNOS
(18) NO-donor compounds
(19) ANG1
(20) Akt
(21) AlP
(22) BMP (bone morphogenetic protein)

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner:

(1) Z-Asp: claims 40, 41, 53, 64
(2) Z-VAD: claims 40, 42, 53, 64
(3) VEGF: claims 40, 43, 45, 53, 64
(4) Bcl-2: claims 40, 53, 64
(5) Bcl-xL: claims 40, 53, 64
(6) acetyl- DEVD-aldehyde inhibitor: claims 40, 53, 64
(7) acetyl-YVAD-aldehyde: claims 40, 53, 64
(8) acetyl-YVAD-chloromethylketone: claims 40, 53, 64
(9) Boc-D- (benzyl) chloromethylketone: claims 40, 53, 64
(10) crmA: claims 40, 53, 64
(11) Zn2+: claims 40, 53, 64
(12) aurintricarboxylic acid: claims 40, 53, 64
(13) cytochalasin B: claims 40, 53, 64
(14) NO: claims 40, 45, 53, 64
(15) eNOS: claims 40, 45, 53, 64
(16) nNOS: claims 40, 45, 53, 64
(17) iNOS: claims 40, 45, 53, 64
(18) NO-donor compounds: claims 40, 45, 53, 64
(19) ANG1: claims 40, 44, 45, 53, 64
(20) Akt: claims 40, 53, 64
(21) AIP: claims 40, 53, 64
(22) BMP (bone morphogenetic protein): claims 40, 53, 64

The following claim(s) are generic: 33, 47, and 58.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the individual agents are structurally and functionally different chemical compounds, having different amino acid sequences and/or structures, and different activities. The methods utilizing the different agents also lack the same or corresponding special technical feature for the same reasons. Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

9. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

12. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jon M. Lockard, Ph.D.
August 6, 2008

/Jon M Lockard/
Examiner, Art Unit 1647